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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,432	07/06/2001	Robert Kleiman	FLORA. 1100	3374

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/899,432	KLEIMAN ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *91-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/26/2007 has been entered.

The amendment received on 02/26/2007, wherein claims 91, 93, 95, 97, 99, 101 have been amended.

Applicant's amendment by deleting "wherein the antiviral activity of the composition is approximately 50 times greater than that of the alcohol component taken alone" is sufficient to overcome the rejection of claims 91-102 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Currently, claims 91-102 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al. (WO 9602244 A1), and further in view of ARQUETTE et al. (WO 9920224).

Katz et al. (5,952,392) discloses that long chain fatty acids broadly including oleic acid (C18, one double bond, see col.2 lines 12-15; col. 3, lines 5-8, col.4, lines 26-28; col.6, lines 28-35) or monounsaturated long chain alcohols broadly (e.g., C18-C28, or octadecenol, docosenol, brassidyl alcohol) in their effective amounts with a physiologically compatible carrier (e.g., cream or ointment applied to skin, or aqueous solution, see col. 12, EXAMPLE 5; Examples 12, 14-15, col.20 lines 34-35, and col.22 lines 39-40 and 64) are useful in a pharmaceutical composition for topical application, intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity. See abstract, col.1 lines 10-15 and 20-47; col.3 lines 18-21; col.7, lines 62-67; col. 12, EXAMPLE 5; Examples 14-15 at col.22-23. It is further disclosed that compositions therein for use in treating viral infections comprise active ingredient or combination of compounds as the active ingredients selected from a group consisting of saturated aliphatic alcohols, mono-unsaturated aliphatic alcohols, mono-unsaturated aliphatic amides and aliphatic acids having a carbon chain length of 18-28 carbons, wherein the active ingredient is present in an amount of 0.1 to about 50 % by

weight of the final composition. See column 6, lines 28-36, lines 50-55. It is taught that the compositions therein are administered to the skin or a mucous membrane topically, parenterally or by transmembranal penetration using a cream, lotion, gel, ointment, suspension, aerosol spray or semi-solid formulation (e.g., a suppository). See column 7, lines 62-67; column 24, claims 7-11.

The prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts, and fatty acid esters herein in a composition for treating virus-induced and inflammatory disease of skin and membranes.

Sintov et al. discloses topical pharmaceutical composition for the treatment of viral infections comprising salts of carboxylic acid such as alkali metal oleates. See abstract; page 2, bottom paragraph; pages 3, lines 1-3, paragraph 5; page 7, EXAMPLE 1.

Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), and the instant fatty acid esters in their various percentages (see pages 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12, especially claim 23). It is also taught that fatty acids such as oleic acid, myristic acid etc are used as emollients. See page 1, lines 24-29.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the monounsaturated long chain alcohols in combination with the long chain fatty acid salt such as alkali metal oleate in a pharmaceutical

composition, in methods for treating virus-induced and inflammatory disease of skin and membranes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant monounsaturated long chain alcohols in combination with long chain fatty acid salt such as alkali metal oleate in a pharmaceutical composition because all active composition components monounsaturated long chain alcohols, and alkali metal salt of fatty acids such as alkali metal salt of oleic acid are known to be useful to treat virus-induced and inflammatory disease of skin and membranes according to Katz et al. (5,952,392), and Sintov et al. It is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to add instantly claimed fatty acid esters to the composition comprising monounsaturated long chain alcohols, and alkali metal salt of oleic acid because Arquette et al. teaches that the instantly claimed fatty acid esters are known to be used as emollients in pharmaceutical compositions. Thus, one of ordinary skill in the art at the time of invention would have been motivated to add the instantly claimed fatty acid esters taught by Arquette et al. to the composition comprising monounsaturated long chain alcohols, and salt of oleic acid with reasonable expectation of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin

and membranes since salts of long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts with a physiologically compatible carrier are known to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity based on Katz et al., and Sintov et al.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant fatty acid esters taught by Arquette et al. with the monounsaturated fatty alcohols, and the salts of oleic acid in a pharmaceutical composition would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes because 1) fatty acid esters are known to be used as an emollients in pharmaceutical composition comprising monounsaturated long chain alcohols, and 2) further according to Arquette emollients have beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin. Thus, one of ordinary skill in the art would have been reasonably expected that the combination of the instant fatty acid esters taught by Arquette et al. with the instant fatty alcohols, and the salts of oleic acid i.e instant salts of fatty acids in a pharmaceutical composition would have at least additive therapeutic effects, and also provide additional benefits such as softening, smoothening of skin.

Claims 93-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392), in view of Sintov et al., and further in view of ARQUETTE et al.

(WO 9920224) as applied to claims 91-92 above, and further in view of Katz (4,874,794) or Katz (5,070,107).

Katz et al., Sintov et al., and ARQUETTE et al. are as discussed above.

Katz et al. (5,952,392) does not explicitly teach the effective amount of monounsaturated alcohol as from about 0.1 mg to about 2 gm per 50 kg of body weight.

Katz et al. (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3 lines 63-68, claims 1-2.

Katz et al. (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, col.3 lines 63-68, claims 1-2.

One of ordinary skill in the art would have been motivated to optimize the effective amounts of instantly claimed long chain monounsaturated alcohols in the composition because Katz et al. '794, and '107 teaches effective amounts of structurally similar long chain fatty alcohols active agents for treating viral infections and skin inflammations as 0.1 mg to 2 g/per 50kg of body weight. Further, it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients,

in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Response to Applicant's Arguments:

Applicant's arguments with respect to rejection of claims 91-102 have been considered but are moot in view of the new ground(s) of rejection, and as found below.

Applicant argues that "In fact, Arquette et al. (WO 9920224) at page 1, lines 24-29, discloses that "[F]atty acids which are used in cosmetics formulations generally include at least stearic acid, oleic acid, myristic acid and palmitic acid" (emphasis added). That notwithstanding, Arquette et al. (WO 9920224) does not disclose, teach or otherwise suggest salts of long chain fatty acids in combination with long chain alcohols as recited in Applicants claims as amended." These remarks have been considered, but not found persuasive because Arquette's reference was employed for its teachings that unsaturated fatty alcohols are combined with instantly claimed unsaturated fatty acid esters in pharmaceutical product for topical application. See page 6, lines 11-15; pages 30, and 33, '224, claims 1, 23.

Applicant argues that "the combination of long chain monounsaturated alcohols and fatty acid salts as claimed in the present invention that create an unexpected, synergistic effect that cannot be deduced from any of the prior art references, either taken alone or in combination." This argument has been considered, but not found persuasive. It is pointed out that the applicant's testing data in the specification at pages 23-26 have been fully considered with respect to the nonobviousness and/or

unexpected synergistic effect of the claimed invention over the prior art, but not deemed persuasive. The results demonstrate that the composition comprising unsaturated fatty alcohols herein has anti-viral effects, as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Note that applicant's remarks with respect to synergistic effect has been considered, but not found persuasive because applicant has not provided any data with respect to the synergistic effect for treating viral infection by combining salts of instant fatty acids with monounsaturated long chain alcohols.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER